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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,454

10/04/2004

Hector Knight Castro

1483 WO/US

2287

7590

11/21/2007

Tim A Cheatham
Mallinckrodt Inc
675 McDonnell Boulevard
PO Box 5840
St Louis, MO 63134

EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

11/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/510,454		KNIGHT CASTRO ET AL.	
	Examiner		Art Unit	
	Melissa Perreira		1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 6-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/4/06, 12/21/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16 are pending in the application.

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-7 and 16 in the reply filed on 9/13/07 is acknowledged.
2. Claims 6-15 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected groups II-IV and nonelected species: acetate and ascorbate, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/13/07.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in EPO on 4/24/02. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Oath/Declaration

One inventor did not sign the oath and declaration.

Specification

The title of the specification does not agree with title provided on the oath and declaration.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Supplement to the Manual and Operating Instructions, FDG Synthesizers, Nuclear Interface GmbH, 11/21/01) in view of Dumhaut et al. (US 6,172,207B1).

6. The Supplement to the Manual and Operating Instructions discloses the method of improving the stability (avoiding decomposition) of a FDG solution. The method involves adjusting the pH of the FDG solution to 5.5 with a buffered product. It is important that the pH of the solution does not reach pH=6 because at this pH considerable degradation starts. The Supplement to the Manual and Operating Instructions does not disclose that the FDG is labeled with 18F or that the buffering agent is citrate.

7. Dumhaut et al. (US 6,172,207B1) discloses an 18F-FDG solution (example; column 6, line 33) where the pH adjustment and isotonicity to injectable standards of the final solution is performed by adding a buffer. The buffer may be a solution of citrate or sodium phosphate, tris or any other injectable buffer (column 5, lines 44-54).

8. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the buffer of Dumhaut et al. (i.e. citrate) for another known

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analogous buffer, such as sodium phosphate for the method of improving the stability of a FDG solution.

Conclusion


No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
November 13, 2007


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER